[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of A Start-Up Commercialization Exclusive License: The Development of Fenoterol Analogues for the Treatment of Brain and Hepatocellular Cancers

AGENCY: National Institutes of Health, HHS

ACTION: Notice

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant to Nova Therapeutics LLC of a start-up exclusive commercialization license to practice the inventions embodied in the following US Provisional Patent Application (and all domestic and foreign counterparts claiming priority to it): Serial No. 61/651,961, filed May 25, 2012, entitled, "Methods of Regulating Cannabinoid Receptor Activity-related Disorders and Diseases" [HHS Ref. E-139-2012/0-US-01]. The patent rights in this invention have been assigned to the Government of the United States of America.

The prospective start-up exclusive commercialization license territory may be worldwide, and the field of use may be limited to:

A worldwide exclusive license to the Patent Rights for research, development, manufacture, distribution, sale, and use in humans for the treatment of brain cancer or hepatocellular cancer within the Licensed Territory, exclusive of (*R,R'*)-4'-methoxy-1-napthylfenoterol (MNF), (*R,S'*)-4'-methoxy-1-napthylfenoterol, (*R,R'*)-ethylMNF, (*R,R'*)-napthylfenoterol, (*R,S'*)-napthylfenoterol, (*R,R'*)-ethyl-napthylfenoterol, and (*R,R'*)-4'-amino-1-napthylfenoterol, (*R,R'*)-4'-hydroxy-1-napthylfenoterol, (*R,R'*)-4-methoxy-ethylfenoterol, (*R,R'*)-methoxyfenoterol, (*R,R'*)-ethylfenoterol, and (*R,R'*)-fenoterol, and the respective stereoisomers of these compounds.

DATE: Only written comments or applications for a license (or both) which are received by the NIH Office of Technology Transfer on or before [Insert date 15 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

ADDRESS: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive commercialization license should be directed to: Patrick McCue, Ph.D., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5560; Facsimile: (301) 402-0220; E-mail: mccuepat@mail.nih.gov.

SUPPLEMENTARY INFORMATION: This invention concerns the discovery by the inventors that specific fenoterol analogues are cannabinoid receptor activators that can inhibit one or more signs or symptoms (such as growth) associated with a tumor that expresses a cannabinoid receptor. Using this discovery, the inventors developed the disclosed methods of treating a tumor expressing a cannabinoid receptor.

The prospective start-up exclusive commercialization license is being considered under the small business initiative launched on 1 October 2011, and will comply with the

terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective start-up exclusive commercialization license may be granted unless the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.7 within fifteen (15) days from the date of this published notice.

Complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive evaluation option license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

April 1, 2013
Date

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Richard U. Rodriguez,
Director
Division of Technology Development & Transfer
Office of Technology Transfer
National Institutes of Health

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